REMARKS

Applicants respectfully request further examination and reconsideration in view of the above amendments and the arguments set forth fully below. In the Office Action mailed August 15, 2006, claims 1-20 have been rejected. In response, the Applicants have submitted the following remarks and amended claim 15. Accordingly, claims 1-20 are still pending. Favorable reconsideration is respectfully requested in view of the amended claims and the remarks below.

Rejections Under 35 §112

Claims 15-19 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, within the Office Action it is stated that with regards to claim 15, the software program is drawn to non-statutory subject matter since it is "functional descriptive material". Within the Office Action it is further stated that there is not a functional inter-relationship between the software program and other claimed elements of the device that permit the functionality to be realized. Accordingly, the Applicants have amended claim 15 according to the Examiner's suggestions. For at least these reasons the Applicants respectfully submit that claim 15 is allowable as being definite and particularly pointing out and distinctly claiming the subject matter which Applicant regards as the invention.

Claim 16-19 are dependent upon the independent claim 15. As is discussed above, the independent claim 15 is allowable as being definite. Accordingly, claims 16-19 are allowable as being dependent upon an allowable base claim.

Rejections Under 35 U.S.C. §102

Claim 20 has been rejected under 35 U.S.C. §102(a) & (e) as being anticipated by U.S. Patent No. 6,668,188 to Sun et al. (hereinafter Sun). The Applicants respectfully disagree with this rejection.

Sun teaches a method of presenting information for evaluating the condition of chronically impaired cardiac patients based on long term assessment of activity trends, using a memoried implanted cardiac rhythm management device having a plurality of programmable parameters and one or more sensors for sensing one or more parameters related to an activity level of the patient (Sun, abstract). Within the Office Action it is stated that Sun teaches gathering patient information from a selected group which includes real-time EGM, activity level and fitness, and drug dosage from column 7, lines 23 to column 8, line 1. While the Sun Patent acquires sensor signal data indicative of the activity level of the patient, the Sun patent does not teach acquiring separate patient data, as well as implant data from an implantable cardiac device. The Sun reference merely teaches collecting a memoried implanted cardiac rhythm management device with a plurality of programmable parameters to acquire data indicative of the activity level of the patient and using that data along with accumulated sensor data to determine the activity level of the patient.

In contrast to the teachings of Sun, the present invention collects both implant data, as well as non-implant data, and synchronizes this data so that the synchronized data can be correlated in a signature pattern and be compared to determine the cardiac condition of the patient. It is important to note that neither Sun, nor any of the other cited references include a system or method that collects both data from an implanted device, as well as separate data from non-implanted means. The present invention is novel as it is able to not only collect both of these types of data, but also synchronizes the data, and correlates the synchronized data to determine a cardiac condition of the patient.

The independent claim 20 is directed to a method of determining a cardiac treatment for a patient having an electronic cardiac implant comprising acquiring patient data, acquiring implant data from the implant, and correlating the patient data and the implant data to determine a cardiac treatment for the patient. As discussed above, Sun does not teach acquiring both patient data as well as implant data from the implant. For at least these reasons, the independent claim 1 is allowable over the teachings of Sun.

Claims 1-3 and 6-12 have been rejected under 35 U.S.C. §102(a) & (e) as being anticipated by U.S. Patent No. 6,647,287 to Peel, III et al. (hereinafter Peel). The Applicants respectfully disagree with this rejection.

Peel teaches a method and system for reconstructing and verifying aortic blood pressure waveforms from peripheral blood pressure waveform data using mathematical models (Peel, abstract). Within the Office Action it is stated that Peel teaches acquiring continuous radial or ulner blood pressure with a tonometer or blood pressure sensor in an artery, and measures and acquires a plethysmographic blood pressure from the patient via their finger. within the Office Action, column 34, lines 23-37 are cited to indicate a teaching of synchronization and correlation of these collected physiological measurements. This citation includes a portion of claim 1 that teaches measuring a continuous radial or ulner blood pressure waveform, measuring a continuous plethysmographic blood pressure waveform, reconstructing aortic blood pressure waveform using mathematical models that combine analytical models of pulse wave propagation, and repeatedly adjusting the mathematical models to the patient and the patient's physiological state based upon the measurements of the ECG, the plethysmograph and the at least one plus oximeter to produce a dynamic, patient specific, reconstructive aortic waveform (Peel, column 34, lines 23-37). However Peel does not actually teach the step of synchronizing the non-implant cardiac data with the implant cardiac data.

In contrast to the teachings of Peel, the system and method of the present invention includes synchronizing the non-implant cardiac data and the implant cardiac data. If the data is not analyzed or reviewed in real-time, the patient monitoring system can assign to the data the date and time when the data was acquired by use of an internal timing system such as an atomic clock. The implant data can be time synchronized with the non-implant data by the patient monitoring system based on the date and time when the implant and the non-implant data was acquired. If implant and non-implant data was not acquired during the same date and time, the implant data can be aligned with the non-implant data

according to one or more fiducial points (present invention, pages 6-7, paragraph 24). The Peel reference does not teach synchronization as is taught and claimed in the present invention.

Claim 1 is directed to a method of analyzing cardiac data acquired from a patient having an electronic cardiac implant comprising acquiring non-implant cardiac data from the patient, acquiring implant cardiac data from the implant, synchronizing the non-implant cardiac data and the implant cardiac data, and correlating the non-implant cardiac data with the implant cardiac data to determine a cardiac condition of the patient. As described above, Peel does not teach synchronizing the non-implant cardiac data and the implant cardiac data. For at least these reasons, the independent claim 1 is allowable over the teachings of Peel. Claims 2 and 3 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Peel. Accordingly, claims 2 and 3 are also allowable as being dependent upon an allowable base claim.

Claim 6 is directed to a method of determining a cardiac treatment for a patient having an electronic cardiac implant comprising acquiring non-implant cardiac data from the patient, acquiring implant cardiac data from the implant, correlating the non-implant cardiac data and the implant cardiac data to generate a signature pattern, and analyzing the signature pattern to determine a cardiac treatment for the patient. It should be further noted that Peel also does not teach generating a signature pattern as is taught and claimed in the present invention. For at least these reasons, the independent claim 6 is allowable over the teachings of Peel.

Claims 7-9 are dependent upon the independent claim 6. As discussed above, the independent claim 6 is allowable over the teachings of Peel. Accordingly, claims 7-9 are also allowable as being dependent upon an allowable base claim.

The independent claim 10 is also a method of developing criteria for diagnosis of cardiac condition in a patient having electronic cardiac implant, and includes the limitation of synchronizing non-implant cardiac data and the implant cardiac data. As

described above, Peel does not teach synchronizing the non-implant cardiac data and the implant cardiac data. For at least these reasons the independent claim 10 is allowable over the teachings of Peel.

Claims 11 and 12 are dependent upon the independent claim 10. as discussed above, the independent claim 10 is allowable over the teachings of Peel. Accordingly, claims 11 and 12 are also allowable as being dependent upon an allowable base claim.

Claims 15, 16 and 19 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,948,005 to Valikai et al. (hereinafter Valikai). The Applicants respectfully disagree with this rejection.

Valikai teaches gathering events/rate data with an implantable pace maker and displaying that data in a histogram format as a function of heart rate and event type, with multiple events being included in the display of each rate bin of the histogram (Valikai, abstract). Within the Office Action, column 17, lines 10-25 is cited as teaching acquiring data from the patient and from the implant. However, after reviewing the cited material in Valikai, it is clear that Valikai merely teaches an implantable pace maker for collecting implanted data, and no other means for collecting data, nor correlating such data, as no correlation occurs if only implantable data collection exists.

In contrast to the teachings of Valikai, the method and system of the present invention teaches and claims collecting not only data from an implantable device, but also non-implantable device data, and synchronizing and correlating these two data collections to diagnose a cardiac condition of a patient.

Claim 15 is directed to a patient monitoring system for analyzing cardiac data acquired from a patient having an electronic cardiac implant comprising a transmitter that generates a polling signal, a receiver that receives implant data when the implant responds to the polling signal, and a computer readable memory encoded with a software and program, the software program sets forth rules for a data acquisition module that acquires implant cardiac data from the implant and non-implant cardiac data from the patient, and an analysis module that correlates the implant cardiac data and the non-implant cardiac

data and generates signature pattern from the correlation. As described above, Valikai does not teach a data acquisition module that acquires non-implant cardiac data from the patient and correlates the implant cardiac data and the non-implant cardiac data. For at least these reasons, the independent claim 15 is allowable over the teachings of Valikai. Claims 16 and 19 are dependent upon the independent claim 15. As discussed above, the independent claim 15 is allowable over the teachings of Valikai. Accordingly, claims 16 and 19 are also allowable as being dependent upon an allowable base claim.

Rejections Under 35 U.S.C. §103

Claims 5 and 14 have been rejected under 35 U.S.C. §103(a) has being unpatentable over Peel as applied to claims 1 and 10, in view of U.S. Patent No. 4,616,333 to Shimoni (hereinafter Shimoni). Claims 5 and 14 are dependent upon the independent claims 1 and 10. As discussed above, the independent claims 1 and 10 are allowable over the teachings of Peel. Accordingly, claims 5 and 14 are also allowable as being dependent upon an allowable base claim.

Claim 17 and 18 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Valikai as applied to claim 15, in further view of U.S. Publication No. 2002/0099302 to Bardy (hereinafter Bardy). Claims 17 and 18 are dependent upon the independent claim 15. As discussed above, the independent claim 15 is allowable over the teachings of Valikai. Accordingly, claim 17 and 18 are also allowable as being dependent upon an allowable base claim.

Claims 4 and 13 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Peel as applied to claims 1 and 10, in further view of U.S. Publication No. 2005/0103351 to Stomberg et al. (hereinafter Stomberg). Claims 4 and 13 are dependent upon the independent claims 1 and 10. As discussed above, the independent claims 1 and 10 are allowable over the teachings of Peel. Accordingly, claims 4 and 13 are also allowable as being dependent upon an allowable base claim.

For these reasons, Applicants respectfully submit that all of the claims are now in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at 414-271-7590 to discuss the same so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,

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